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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,526

03/10/2004

Michael John Cuppy

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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

05/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/797,526	<b>Applicant(s)</b> CUPPY, MICHAEL JOHN	
	<b>Examiner</b> SHEFALI D. PATEL	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Acknowledgments***

1. In the reply, filed on February 28, 2008, Examiner acknowledges the amendments to claims 1-11, 15, 19, 23, and 24.
2. Examiner acknowledges the amendments to the title and abstract.
3. Currently, claims 1-24 are pending for examination.

### ***Response to Arguments***

4. Applicant's arguments filed February 28, 2008, have been fully considered but they are not persuasive because the arguments are intended use recitations:

In regards to claims 1, 4, 5, 11, 19, 21, 22, and 24, in response to applicant's argument that the device of Inman et al (US 4,578,063) does not disclose a swivel joint that could be combined with the Cuppy (US 5,755,709) patent to obtain the claimed invention, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim:

Applicant argues that since the device of Inman et al is implanted into the body with the swivel joint [42] implanted into the body, the device will encourage ingrowth of connective tissue and vascularization leading to the eventual inability of the swivel joint to rotate relative to the device (Reply, page 10, paragraph 2). Examiner agrees with this rationale that the connective

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tissue and the vasculature will grow to surround the device and prevent rotation of the swivel joint; however, Examiner is only using the structural concept of the swivel joint of Inman et al to modify the device of Cuppy so that the subhousing of Cuppy will be able to move within various bends or angles (Inman et al, column 8, lines 39-42) enabling the subhousing to be moved in a direction that is more comfortable for the patient. Examiner does not intend for the swivel joint to be implanted into the body, as the subhousing of Cuppy, which is being modified by the swivel joint of Inman et al, will remain outside of the body. Connective tissue and vasculature will not grow around the device as the device will remain outside of the body, and only the catheter that is attached to the device is inserted into the body.

Applicant states the intended use of the device of claims 1, 11, 19, and 24, as the device will allow repositioning of the second end of the subhousing relative to the housing (Reply, page 11, paragraph 1). Applicant states that the swivel joint of Inman et al was designed to be implanted under the skin of the patient (Reply, page 11, paragraph 3); however, such is an intended use recitation of the swivel joint of Inman et al. A swivel joint can be positioned inside or outside of the body. Based on its structure alone, if the swivel joint of Inman et al is applied to the subhousing of Cuppy, then the subhousing will be able to move relative to the housing. The prior art structure of the modified device of Cuppy and Inman et al is capable of performing the claimed intended use.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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~~(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.~~

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6. Claims 1-3, 6-20, 23, and 24 is rejected under 35 U.S.C. 103(a) as being unpatentable

over Cuppy (US 5,755,709), as applied to claim 23 above, in view of Inman et al (US

4,578,063).

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In regards to claim 1, Cuppy teaches a catheter adapter device (Figure 2) comprising:

- a. a housing (cylindrical body section of housing [28]) having a distal end, a proximal end, and defining a cavity, the proximal end being adapted to connect to a catheter (catheter tube [30])
- b. a self-sealing injection port (self-sealing injection port [40]) in fluid communication with the cavity (column 6, lines 21-26).
- c. a subhousing (coupling/vent cap region of housing [46]) having a first end and a second end and defining a cavity, the subhousing cavity in fluid communication with the housing cavity (Figure 2)
- d. a unidirectional fluid valve (check valve [38]) permitting solution flow from the subhousing to the housing while substantially preventing solution flow from the housing to the subhousing (column 6, lines 17-21 and lines 33-38) (column 10, lines 21-32).

Cuppy does not teach that the subhousing is movably connected at the first end to the housing so that the position of the second end of the subhousing relative to the housing can be selectively adjusted within a range of positions. Inman et al teaches a swivel connector [42] between an implant device [10] and an internal body conduit [44] to allow for proper placement of the internal body conduit with respect to the implant device and to the patient's body (column 7,

lines 44-45; column 8, lines 36-42). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the swivel joint taught by Inman et al between the subhousing and the housing of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8, lines 39-42) enabling the subhousing to be moved in a direction that is more comfortable for the patient's body.

In regards to claim 11, Cuppy teaches an apparatus (Figures 1-2) comprising:

- a. a catheter (Figure 1, catheter tube [30]) adapted for entry into a vascular system (column 5, line 57)
- b. a catheter adapter device (Figure 2), removably connected to the catheter (column 6, lines 8-12), having:
  - i. a hollow housing (cylindrical body section of housing [28]) having a distal end, a proximal end, and defining a cavity, the proximal end being adapted to connect to a catheter (catheter tube [30])
  - ii. a self-sealing injection port (self-sealing injection port [40] in fluid communication with the cavity (column 6, lines 21-26)
- c. a subhousing (coupling/vent cap region of housing [46]) having a first end and a second end and defining a cavity, the subhousing cavity in fluid communication with the housing cavity (Figure 2)
- d. a unidirectional fluid valve permitting solution flow from the subhousing to the housing while substantially preventing solution flow from the housing to the subhousing

(Figure 2, check valve [38];) (column 6, lines 17-21 and lines 33-38) (column 10, lines 21-32).

Cuppy does not teach that the subhousing is movably connected at the first end to the housing so that the position of the second end of the subhousing relative to the housing can be selectively adjusted within a range of positions. Inman et al teaches a swivel connector [42] between an implant device [10] and an internal body conduit [44] to allow for proper placement of the internal body conduit with respect to the implant device and to the patient's body (column 7, lines 44-45; column 8, lines 36-42). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the swivel joint taught by Inman et al between the subhousing and the housing of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8, lines 39-42) enabling the subhousing to be moved in a direction that is more comfortable for the patient's body.

In regards to claims 2 and 12, Cuppy teaches that the housing [28] is generally linearly aligned so that the self-sealing injection port [40] is opposite the proximal end (Figure 2).

In regards to claims 3 and 13, Cuppy does not teach that the subhousing is connected to the housing via a swivel joint. Inman et al teaches a swivel connector [42] between an implant device [10] and an internal body conduit [44] (column 7, lines 44-45; column 8, lines 36-42). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the swivel joint taught by Inman et al between the subhousing and the housing of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8,

lines 39-42) that allow the subhousing to be moved in a direction that is more comfortable for the patient's body.

In regards to claims 6 and 14, Cuppy does not teach a second self-sealing injection port that is connected to the subhousing, but Cuppy does teach one self-sealing injection port in fluid communication with the cavity of the housing (Figure 2, self-sealing injection port [40]; column 6, lines 21-26). To a person having ordinary skill in the art, the purpose of the self-sealing injection port is to permit the patient to be medicated (column 4, lines 16-18) while maintaining sterile conditions between the device and the patient. Cuppy teaches that at the free end of the subhousing, an IV line can be connected (column 6, lines 37-38) and that a second IV line can be connected to the self-sealing injection port of the housing for medicament administration (column 4, lines 27-30). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the self-sealing injection port of the housing taught by Cuppy to the subhousing of Cuppy in order to provide a self-seal between the IV line and the subhousing and to maintain sterile conditions between the device and the patient at the subhousing site.

In regards to claims 7 and 15, Cuppy teaches that a first part of the subhousing [46] terminates at the first end of the subhousing, a second part of the subhousing terminates at the second end of the subhousing, and the first and second parts of the subhousing are joined at an angle of approximately 90 degrees (Figure 2).

In regards to claim 8, Cuppy teaches a cap (vent cap [24]) for sealing the second end of the subhousing [46] (Figure 2) (column 6, lines 12-15).



In regards to claims 9 and 16, Cuppy teaches that the fluid valve (check valve [38]) is carried within the housing (column 6, lines 18-19).

In regards to claims 10 and 17, Cuppy teaches that the fluid valve [38] includes a movable disk-shaped element, as can be seen by the disk shape of the fluid valve [38] in Figure 2 (column 6, lines 17-19).

In regards to claim 18, Cuppy teaches a needle (needle [18]) received within the catheter [30] (Figure 8).

In regards to claim 19, Cuppy teaches a method comprising:

- a. providing a catheter adapter device having
  - i. a hollow housing (cylindrical body section of housing [28]) having a distal end, a proximal end, and defining a cavity (Figure 2)
  - ii. a self-sealing injection port (self-sealing injection port [40]) in fluid communication with the cavity (Figure 2) (column 6, lines 21-26)
  - iii. a subhousing (coupling/vent cap region of housing [46]) having a first end a second end and defining a cavity, the subhousing cavity in fluid communication with the housing cavity (Figure 2)
  - iv. a unidirectional fluid valve (check valve [38]) (column 6, lines 17-21 and lines 33-38) permitting solution flow from the subhousing to the housing while substantially preventing solution flow from the housing to the subhousing (column 10, lines 21-32)

- b. connecting the catheter adapter device to a catheter (catheter tube [30]) at its proximal end (column 15, lines 30-31)
- c. connecting the catheter adapter device to a fluid line at one end of the subhousing (column 6, lines 36-38)
- d. flowing fluid from the subhousing to the housing and through the fluid valve (column 6, lines 17-21 and lines 33-38).

Cuppy does not teach that the subhousing is movably connected at one end to the housing so that the position of the other end of the subhousing relative to the housing can be selectively adjusted within a range of positions. Inman et al teaches a swivel connector [42] between an implant device [10] and an internal body conduit [44] to allow for proper placement of the internal body conduit with respect to the implant device and to the patient's body (column 7, lines 44-45; column 8, lines 36-42). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the swivel joint taught by Inman et al between the subhousing and the housing of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8, lines 39-42) enabling the subhousing to be moved in a direction that is more comfortable for the patient's body.

In regards to claim 20, Cuppy teaches withdrawing fluid within the housing through the self-sealing injection port (column 15, lines 37-39; column 16, lines 38-39).

In regards to claim 23, Cuppy teaches a catheter adapter device (Figure 2) comprising:

- a. a hollow housing (cylindrical body section of housing [28]) having a distal end, a proximal end, and defining a cavity, the proximal end removably connected to a catheter

(catheter tube [30]) having an elongated catheter sheath extending in a predetermined direction (Figure 2) (column 6, lines 8-12)

- b. a self-sealing injection port (self-sealing injection port [40]) in fluid communication with the cavity (column 6, lines 21-26).
- c. a subhousing (coupling/vent cap region of housing [46]) having a first end and a second end defining a cavity therethrough, the first end connected to the housing [28] and the second end capable of connection to an IV line, wherein a first part of the subhousing terminates at the first end of the subhousing, a second part of the subhousing terminates at the second end of the subhousing, and the first and second parts of the subhousing are joined at an angle of approximately 90 degrees so that the housing and subhousing together are capable of defining a generally U-shaped structure (Figure 2) (column 10, lines 56-57)
- d. a unidirectional fluid valve (check valve [38]) permitting solution flow from the subhousing to the housing while substantially preventing solution flow from the housing to the subhousing (Figure 2) (column 6, lines 17-21 and lines 33-38) (column 10, lines 21-32).

Cuppy does not teach that the subhousing is rotatably connected at one end to the housing so that the position of the other end of the subhousing relative to the housing can be selectively adjusted within a range of positions. Inman et al teaches a swivel connector [42] between an implant device [10] and an internal body conduit [44] to allow for proper placement of the internal body conduit with respect to the implant device and to the patient's body (column 7, lines 44-45; column 8, lines 36-42). It would have been obvious to a person having ordinary skill in the art at

the time the invention was made to apply the swivel joint taught by Inman et al between the subhousing and the housing of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8, lines 39-42) enabling the subhousing to be moved in a direction that is more comfortable for the patient's body.

In regards to claim 24, Cuppy does not teach that the first end of the subhousing is connected to the housing via a swivel joint. Inman et al teaches a swivel connector [42] between an implant device [10] and an internal body conduit [44] (column 7, lines 44-45; column 8, lines 36-42). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the swivel joint taught by Inman et al between the subhousing and the housing of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8, lines 39-42) that allow the subhousing to be moved in a direction that is more comfortable for the patient's body.

7. .... Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cuppy and Inman et al, as applied to claim 3 above, and further in view of Black (US 5,092,854).

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In regards to claim 4, Cuppy does not teach a swivel joint that provides a 360 degree range of motion. While Inman et al teaches the application of a swivel connector (column 7, lines 44-45; column 8, lines 36-42), Inman et al is silent about the range of motion of the swivel joint. However, Black teaches a swivel connector with 360° of motion (column 2, lines 64-68) so that a tip, such as the subhousing, can be oriented in any desired direction (column 1, lines 67-68 to column 2, lines 1-2). It would have been obvious to a person having ordinary skill in the art at

the time the invention was made to apply the swivel connector taught by Inman et al and Black between the subhousing and housing of Cuppy so that the subhousing can be moved in any direction, within 360° of motion, that is more comfortable for the patient's body based on complete range of motion.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cuppy and Inman et al, as applied to claim 1 above, and further in view of Ryan (US 5,338,314).

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In regards to claim 5, Cuppy does not teach a luer-style connector for securing the housing to the catheter. Ryan teaches that a luer is provided between a Y-connector body and a catheter (column 1, lines 67-68). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the luer-style connector taught by Ryan to the modified device of Cuppy because Ryan teaches that a luer-style connector not only connects a catheter to a housing, but it also provides an effective seal between the catheter and the housing (column 3, lines 35-42).

9. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuppy and Inman et al, as applied to claim 19 above, and further in view of Merry et al (US 4,929,235).

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In regards to claims 21 and 22, Cuppy does not teach of inserting a wire-based treatment device, such as a guide wire, a balloon catheter, or a pressure sensor, through the self-sealing injection port and into the vascular system of the patient. Merry et al teaches that tubes such as balloon catheters can be inserted into the body by way of a self-sealing valve-gasket (column 1, lines 7-17). It would have been obvious to a person having ordinary skill in the art at the time the

invention was made to insert such a wire-based treatment device as taught by Merry et al through the modified device of Cuppy since certain medical procedures often require one tube to be inserted into another tube into a vessel with the second tube being sealed at all times (column 1, lines 13-17) to maintain a sterile medical environment.

### *Conclusion*

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571)270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/  
Examiner, Art Unit 3767  
05/13/2008

/Kevin C. Sirmons/  
| Supervisory Patent Examiner, Art Unit 3767